

Attorney Docket No.: DEX-0245
Inventors: Recipon et al.
Serial No.: 10/034,934
Filing Date: October 26, 2001
Page 4

REMARKS

Claims 1-17 are pending in the instant application. Claims 6 and 10-17 have been withdrawn from consideration and subsequently canceled without prejudice by Applicants by this amendment. Claims 1 have been amended. Support for these amendments is provided in the specification at page 1, lines 9-18, page 6, lines 12-15, page 15, lines 22-27, page 32, line 31 through page 33, line 3 and Example 1. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed August 1, 2003. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled without prejudice non-elected claims 6 and 10-17. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Objection to Claims 1-5 and 7-9

Claims 1-5 and 7-9 have been objected to as reciting non-elected subject matter. Thus, Applicants have amended the claims to be drawn to the elected nucleic acid sequence of SEQ ID NO: 8

Attorney Docket No.: DEX-0245
Inventors: Recipon et al.
Serial No.: 10/034,934
Filing Date: October 26, 2001
Page 5

encoding SEQ ID NO:87 and its related sequence, SEQ ID NO:7. The relationship of SEQ ID NO:7 and 8 is clear from the sequence listing. Accordingly, inclusion of this sequence in the prosecution of this case is respectfully requested.

Withdrawal of this objection is respectfully requested in light of the amendments to the claims.

III. Rejection of Claims 1-5 and 7-9 under 35 U.S.C. § 112, second paragraph

Claims 1-5 and 7-9 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner suggests that the claims are indefinite over recitation of "selectively hybridizes" because it is not clear what conditions permit selective hybridization.

Applicants respectfully disagree as what it meant by the phrase "selectively hybridizes" is clear and definite when read in light of the teachings of the specification at page 14, lines 11-18.

However, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims in accordance with

Attorney Docket No.: DEX-0245
Inventors: Recipon et al.
Serial No.: 10/034,934
Filing Date: October 26, 2001
Page 6

teachings at page 15, lines 22-27, to include conditions permitting hybridization.

Withdrawal of this rejection under 35 U.S.C. § 112, second paragraph, is therefore respectfully requested.

IV. Rejection of Claims 1-5 and 7-9 under 35 U.S.C. § 112, first paragraph - Written Description

Claims 1-5 and 7-9 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner suggests that claims reciting 60% sequence identity and "selective hybridization" to a nucleic acid are inclusive of sequence from other species, mutated sequences and allelic variants having different functional activities than that of the nucleic acid (SEQ ID NO:8) encoding the polypeptide of SEQ ID NO:87. Thus, the Examiner suggests that the claims include a large genus of nucleic acids encoding polypeptides, having unique functional activities, whereas applicants only disclose one member of the genus.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1, part (c), to state that the nucleic acid sequence hybridizes under stringent conditions and have defined these conditions in accordance with

Attorney Docket No.: DEX-0245
Inventors: Recipon et al.
Serial No.: 10/034,934
Filing Date: October 26, 2001
Page 7.

teachings at page 14, line 17, through page 16, line 30. Applicants have amended part (d) of claim 1 to state that the nucleic acid sequence has 85% identity in accordance with teachings at page 32, line 31 through page 33, line 3. Further, in accordance the teachings of Example 1, Applicants have amended claim 1 to state that the nucleic acid molecule is lung cancer specific.

Detailed methodologies for ascertaining sequences which meet the structural and functional limitations of the instant amended claims are set forth in the specification at page 13, line 5, through page 14, line 10, and page 14, line 11 through page 16, line 32 and Example 1. Further methods for assessing percent sequence identity and/or the ability of a nucleic acid sequence to hybridize under stringent conditions to a disclosed reference sequence are performed routinely by those skilled in the art. Thus, upon discovery of the instant claimed nucleic acid sequence of SEQ ID NO:7 or 8 and its expression in lung cancer tissues, Applicants were clearly in possession of additional nucleic acid sequences identified in accordance with routine procedures based upon this reference sequence. Further, the instant specification and its teachings clearly place the public in possession of these sequences as well.

Attorney Docket No.: DEX-0245
Inventors: Recipon et al.
Serial No.: 10/034,934
Filing Date: October 26, 2001
Page 8

Thus, the instant specification and the claims as amended meet the "essential goal" of the written description requirements of 35 U.S.C. § 112, first paragraph as set forth in MPEP § 2163.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

V. Rejection of Claims 1-5 and 7-9 under 35 U.S.C. § 112, first paragraph

Claims 1-5 and 7-9 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. In particular, the Examiner suggests that claim 1(c) and (d) are drawn to sequences from other species, mutated sequences, and allelic variants having different functional activities than that of the nucleic acid (SEQ ID NO:8) encoding the polypeptide of SEQ ID NO:87.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims in accordance with teachings of Example 1 to clarify that the claimed sequences share the functional activity of being lung cancer specific. Further, as discussed in Section V, *supra*, Applicants have amended part (c) of claim 1 to specify hybridization conditions for stringently hybridizing nucleic acid molecules and part (d) to state 85%

Attorney Docket No.: DEX-0245
Inventors: Recipon et al.
Serial No.: 10/034,934
Filing Date: October 26, 2001
Page 9

sequence identity. Methodologies for identifying nucleic acid molecules with these claimed structural and functional characteristics are set forth in detail in the specification at page 13, line 5, through page 14, line 10, and page 14, line 11 through page 16, line 32 and Example 1. Thus, the specification teaches one of skill in the art how to make and use the lung cancer specific nucleic acids as defined by the claims. Accordingly, the instant specification meets the requirements of 35 U.S.C. § 112, first paragraph, as set forth in MPEP 2164.

Withdrawal of this rejection is therefore respectfully requested.

VI. Rejection of Claims 1-2 and 4-5 under 35 U.S.C. § 102(a), 102(b), or 102(f)

Claims 1-2 and 4-5 have been rejected under 35 U.S.C. § 102(a) and 102(b) as being anticipated by LIFESEQ™ Database. The Examiner suggests that "the specification states at page 116 that the nucleic acids of the present invention were procured from, and thereby known by Incyte Genomics Inc. at the time the invention was made". Thus, the Examiner suggests that the nucleic acids of the present invention were known and used in the art prior to the filing of the instant application, were in public use and on sale

Attorney Docket No.: DEX-0245
Inventors: Recipon et al.
Serial No.: 10/034,934
Filing Date: October 26, 2001
Page 10

in this country prior to filing the instant application. Further, the Examiner suggests that this statement is indicative of the sequence being known by Incyte Genomics at the time the invention was made and therefore not invented by Applicants.

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully disagree with the Examiner's characterization of the teachings of the specification at page 116. Contrary to the Examiner's suggestion, nowhere do Applicants "state" in the instant patent application that "the nucleic acids of the present invention were procured from, and thereby known by Incyte Genomics Inc. at the time the invention was made". Instead, what is taught in Example 1 beginning at page 116 of the instant specification are the steps utilized by Applicants, not Incyte Genomics Inc. to identify the lung cancer specific nucleic acid molecules of the present invention. As clearly stated in this Example, Applicants utilized their own set of algorithms referred to as CLASP™ to systematically interrogate and analyze gene expression data in the LIFESEQ Gold database. It is only by this systematic analysis wherein CLASP categorizes ESTs and genes by disease class and performs simultaneous parallel searching for ESTs and genes expressed selectively in defined tissue types and

Attorney Docket No.: DEX-0245
Inventors: Recipon et al.
Serial No.: 10/034,934
Filing Date: October 26, 2001
Page 11

cancer disease states that the lung specific nucleic acid molecules of SEQ ID NO:7 and 8, encoding SEQ ID NO: 87 were identified.

But for applicants proprietary CLASP™ algorithms and the disclosure of the subject application, one of skill in the art would not know that the claimed lung cancer specific nucleic acids including SEQ ID No:7 or 8 are lung specific or cancer specific, much less lung cancer specific.

In an earnest effort to clearly distinguish the present invention from expression data in the LIFESEQ Gold database, Applicants have amended claim to clarify that the isolated nucleic acid molecules are lung cancer specific. Support for this amendment is provided in Example 1 beginning at 116 wherein Applicants describe use of their CLASP™ algorithms to analyze and identify SEQ ID NO:7 and 8 as having CLASP2, meaning detectable expression only in cancer tissue, profiles.

While sequences or portions thereof may have been in the LIFESEQ database, the Examiner has not shown that the claimed lung cancer specific nucleic acids including SEQ ID NO:7 or 8 are disclosed. Accordingly, the LIFESEQ database cannot anticipate the claims as amended.

Withdrawal of these rejections under 35 U.S.C. § 102(a), 102(b) and 102(f) is therefore respectfully requested.

Attorney Docket No.: DEX-0245
Inventors: Recipon et al.
Serial No.: 10/034,934
Filing Date: October 26, 2001
Page 12

VII. Rejection of Claims 7-9 under 35 U.S.C. § 103(a)

Claims 7-9 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over LIFESEQ™ Database, in view of Prendergast (U.S. Patent 5,958,753). The Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have linked the polynucleotides of the LIFESEQ database into expression vectors to have transformed host cells with the resulting vectors and to have used the transformed cells to express polypeptides in order to have provided an effective means for synthesizing polypeptides encoded by the isolated polynucleotides in light of the teachings of Prendergast.

Applicants respectfully traverse this rejection.

At the outset, as discussed in Section V, supra, Applicants respectfully disagree with the Examiner's characterization of the teachings of the specification which are reiterated in this rejection. Contrary to the Examiner's suggestion, nowhere do Applicants "state" in the instant patent application that "the nucleic acids of the present invention were procured from, and thereby known by Incyte Genomics Inc. at the time the invention was made".

Attorney Docket No.: DEX-0245
Inventors: Recipon et al.
Serial No.: 10/034,934
Filing Date: October 26, 2001
Page 13

As made clear in the teachings of the Example 1 beginning at page 116, Applicants, using their CLASP algorithms identified the lung cancer specific nucleic acid molecules of the present invention.

Thus, it is only with the instant specification in hand, and not merely sequence and expression data as set forth in the LIFESEQ database, that one of skill would be motivated to link the claimed lung cancer specific nucleic acid molecules into vectors and express such vector in host cells.

Accordingly, the combination of cited references provides neither the requisite motivation to combine their teachings nor a teaching of all claim limitations of the claims, now amended to clarify that the isolated nucleic acid molecules are lung cancer specific, to render the instant invention prima facie obvious. See MPEP § 2143.

Thus, withdrawal of this rejection under 35 U.S.C. § 103 (a) is respectfully requested.

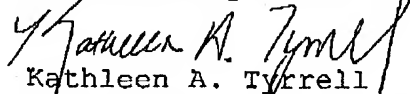
VIII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

Attorney Docket No.: DEX-0245
Inventors: Recipon et al.
Serial No.: 10/034,934
Filing Date: October 26, 2001
Page 14

favorable reconsideration and subsequent allowance of the pending
claims is earnestly solicited.

Respectfully submitted,


Kathleen A. Tyrrell
Registration No. 38,350

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LICATA & TYRRELL P.C.
66 E. Main Street
Marlton, NJ 08053
856-810-1515